Individual Safety Report

3549324-0-00-01

McNeil Consumer Healthcare

McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

A Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	adult	( )female (X)male	unk lbs or kgs

B Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
(x) other: none

3. Date of event (mo/day/yr): 1995/1996

4. Date of this report (mo/day/yr): 10/15/99

5. Describe event or problem

Consumer report received via Internet alleges that the use of an unknown TYLENOL® acetaminophen product was associated with LIVER DAMAGE. According to consumer's Internet report, on an unspecified date in 1995 or 1996, he took an unspecified dose of an unknown TYLENOL® product with concomitant use of alcohol. He reportedly experienced permanent LIVER DAMAGE. No further information was provided.

6. Relevant tests/laboratory data, including dates

unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

consumer's Internet report indicates concomitant use of alcohol

C Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL product

#2

2. Dose, frequency & route used

#1 unknown dose, po

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 1995/1996; 1 day

#2

4. Diagnosis for use (indication)

#1 unknown

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 unknown

#2

7. Exp. date (if known)

#1 unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

G All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-273-7303

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
(x) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
(x) other: Internet

4. Date received by manufacturer (mo/day/yr): 10/06/99

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day ( ) 15-day
( ) 10-day (X) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

LIVER DAMAGE

9. Mfr. report number

1248560A

E Initial reporter

1. Name, address & phone #

AUG - 9 2000

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes ( ) No		( ) Yes ( ) No ( ) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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